

Substitute for form 1449A&B/PTO				Complete If Known	
INFORMATION DISCLOSURE STATEMENT BY APPLICANT				Application Number	10/815,340
(Use as many sheets as necessary)				Filing Date	March 30, 2004
				First Named Inventor	Berzofsky, Jay A.
				Art Unit	1645
				Examiner Name	Nicole Kinsey
Sheet	1	of	2	Attorney Docket Number	015280-368240US

NON PATENT LITERATURE DOCUMENTS					
Examiner Initials *	Cite No. ¹	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.			T ²
/NK/	AA	Ahmed and Gray, "Immunological memory and protective immunity: understanding their relation," <i>Science</i> 272:54-60 (1996).			<input type="checkbox"/>
	AB	Bender <i>et al.</i> , "Oral immunization with a replication-deficient recombinant vaccinia virus protects mice against influenza," <i>J. Virol.</i> 70:6418-6424 (1996).			<input type="checkbox"/>
	AC	Bennink <i>et al.</i> , "Influenza pneumonia: early appearance of cross-reactive T cells in lungs of mice primed with heterologous type A viruses," <i>Immunol.</i> 35:503-509 (1978).			<input type="checkbox"/>
	AD	Chen <i>et al.</i> , "Predominant T-cell receptor V β usage of intraepithelial lymphocytes during the immune response to enteric reovirus infection," <i>J. Virol.</i> 71:3431-3436 (1997).			<input type="checkbox"/>
	AE	Ehl <i>et al.</i> , "A functional and kinetic comparison of antiviral effector and memory cytotoxic T lymphocyte populations <i>in vivo</i> and <i>in vitro</i> ," <i>Eur. J. Immunol.</i> 27:3404-3413 (1997).			<input type="checkbox"/>
	AF	Epstein <i>et al.</i> , "Mechanism of protective immunity against influenza virus infection in mice without antibodies," <i>J. Immunol.</i> 160:322-327 (1998).			<input type="checkbox"/>
	AG	Gallican and Rosenthal, "Long-lived cytotoxic T lymphocyte memory in mucosal tissues after mucosal but not systemic immunization," <i>J. Exp. Med.</i> 184:1879-1890 (1996).			<input type="checkbox"/>
	AH	Gurgo <i>et al.</i> , "Envelope sequences of two new United States HIV-1 isolates," <i>Virology</i> 164:531-536 (1988).			<input type="checkbox"/>
↓	AI	Kulkarni <i>et al.</i> , "Cytotoxic T cells specific for a single peptide on the M2 protein of respiratory syncytial virus are the sole mediators of resistance induced by immunization with M2 encoded by a recombinant vaccinia virus," <i>J. Virol.</i> 69:1261-1264 (1995).			<input type="checkbox"/>
/NK/	AJ	Kundig <i>et al.</i> , "On the role of antigen in maintaining cytotoxic T-cell memory," <i>Proc. Natl. Acad. Sci. USA</i> 93:9716-9723 (1996).			<input type="checkbox"/>

Examiner Signature	/Nicole Kinsey/	Date Considered	12/10/2007
--------------------	-----------------	-----------------	------------

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 809. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

¹Applicant's unique citation designation number (optional). ²Applicant is to place a check mark here if English language Translation is attached.

Substitute for form 1449A&B/PTO				Complete If Known	
				<i>Application Number</i>	10/815,340
				<i>Filing Date</i>	March 30, 2004
				<i>First Named Inventor</i>	Berzofsky, Jay A.
				<i>Art Unit</i>	1645
				<i>Examiner Name</i>	Nicole Kinsey
Sheet	2	of	2	Attorney Docket Number	015280-368240US

NON PATENT LITERATURE DOCUMENTS					
Examiner Initials *	Cite No. ¹	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.			T ²
/NK/	AK	Lohman <i>et al.</i> , "Antiviral cytotoxic T lymphocytes in vaginal mucosa of simian immunodeficiency virus-infected rhesus macaques," <i>J. Immunol.</i> 155:5855-5860 (1995).			<input type="checkbox"/>
	AL	Miller <i>et al.</i> , "Rhesus macaques previously infected with simian/human immunodeficiency virus are protected from vaginal challenge with pathogenic SIVmac239," <i>J. Virol.</i> 71:1911-1921 (1997).			<input type="checkbox"/>
	AM	Putkonen <i>et al.</i> , "Protection of human immunodeficiency virus type 2-exposed seronegative macaques from mucosal simian immunodeficiency virus transmission," <i>J. Virol.</i> 71:4981-4984 (1997).			<input type="checkbox"/>
	AN	Quesada-Rolander <i>et al.</i> , "Protection against mucosal SIV _{sm} challenge in macaques infected with a chimeric SIV that expresses HIV type 1 envelope," <i>AIDS Res. Hum. Retroviruses</i> 12:993-999 (1996).			<input type="checkbox"/>
	AO	Ratner <i>et al.</i> , "Complete nucleotide sequence of the AIDS virus, HTLV-III," <i>Nature</i> 313:277-284 (1985).			<input type="checkbox"/>
	AP	Rosenthal and Gallichan, "Challenges for vaccination against sexually-transmitted diseases: induction and long-term maintenance of mucosal immune responses in the female genital tract," <i>Semin. Immunol.</i> 9:303-314 (1997).			<input type="checkbox"/>
	AQ	Sydora <i>et al.</i> , "Intestinal intraepithelial lymphocytes respond to systemic lymphocytic choriomeningitis virus infection," <i>Cell. Immunol.</i> 167:161-169 (1996).			<input type="checkbox"/>
	AR	Takahashi <i>et al.</i> , "A single amino acid interchange yields reciprocal CTL specificities for HIV-1 gp160," <i>Science</i> 246:118-121 (1989).			<input type="checkbox"/>
↓	AS	Taylor and Askonas., "Influenza nucleoprotein-specific cytotoxic T-cell clones are protective <i>in vivo</i> ," <i>Immunol.</i> 58:417-420 (1986).			<input type="checkbox"/>
/NK/	AT	Wang <i>et al.</i> , "Mucosal immunization with a DNA vaccine induces immune responses against HIV-1 at a mucosal site," <i>Vaccine</i> 15:821-825 (1997).			<input type="checkbox"/>

Examiner Signature	/Nicole Kinsey/	Date Considered	12/10/2007
--------------------	-----------------	-----------------	------------

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

¹Applicant's unique citation designation number (optional). ²Applicant is to place a check mark here if English language Translation is attached.

Substitute for form 1449A&B/PTO				Complete if Known	
INFORMATION DISCLOSURE STATEMENT BY APPLICANT <i>(Use as many sheets as necessary)</i>				<i>Application Number</i>	10/815,340
				<i>Filing Date</i>	March 30, 2004
				<i>First Named Inventor</i>	Berzofsky, Jay A.
				<i>Art Unit</i>	1645
				<i>Examiner Name</i>	Nicole Kinsey
Sheet	1	of	5	<i>Attorney Docket Number</i>	015280-368240US

FOREIGN PATENT DOCUMENTS							
Examiner Initials*	Cite No. ¹	Foreign Patent Document			Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
		Country Code ³	Number ⁴	Gnd Code ⁵ (if known)			
/NK/	AE	PCT	WO 87/07616		12/17/1987		
/NK/	AF	PCT	0 273 716		12/23/1987		
/NK/	AG	PCT	WO 94/26785		11/24/1994		

Examiner Signature	/Nicole Kinsey/	Date Considered	12/10/2007
--------------------	-----------------	-----------------	------------

EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

1. Applicant's unique citation designation number (optional).² Applicant is to place a check mark here if English language Translation is attached.

Substitute for form 1449A&B/PTO				Complete if Known	
INFORMATION DISCLOSURE STATEMENT BY APPLICANT				<i>Application Number</i>	10/815,340
<i>(Use as many sheets as necessary)</i>				<i>Filing Date</i>	March 30, 2004
				<i>First Named Inventor</i>	Berzofsky, Jay A.
				<i>Art Unit</i>	1645
				<i>Examiner Name</i>	Nicole Kinsey
Sheet	2	of	5	<i>Attorney Docket Number</i>	015280-368240US

NON PATENT LITERATURE DOCUMENTS					
Examiner Initials *	Cite No. ¹	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.			T ²
/NK/	AH	Ahlers <i>et al.</i> , "Construction of an HIV-1 Peptide Vaccine Containing a Multideterminant Helper Peptide Linked to a V3 Loop Peptide 18 Inducing Strong Neutralizing Antibody Responses in Mice of Multiple MHC Haplotypes after Two Immunizations," <i>J. Immunol.</i> 150:5647-5665 (1993).			<input type="checkbox"/>
	AI	Ahlers <i>et al.</i> , "Candidate HIV Type 1 Multideterminant Cluster Peptide-P18MN Vaccine Constructs Elicit Type 1 Helper T Cells, Cytotoxic T Cells, and Neutralizing Antibody, all Using the Same Adjuvant Immunization," <i>AIDS Res. Hum. Retroviruses</i> 12:259-272 (1996).			<input type="checkbox"/>
	AJ	Ahlers <i>et al.</i> , "Cytokine-in-Adjuvant Steering of the Immune Response Phenotype to HIV-1 Vaccine Constructs," <i>J. Immunol.</i> 158:3947-3958 (1997).			<input type="checkbox"/>
	AK	Ahlers <i>et al.</i> , "Enhanced Immunogenicity of HIV-1 Vaccine Construct by Modification of the native Peptide Sequence," <i>Proc. Natl. Acad. Sci. USA</i> 94:10856-10861 (1997).			<input type="checkbox"/>
	AL	Belyakov <i>et al.</i> , "Mucosal Immunization with HIV-1 Peptide Vaccine Induces Mucosal and Systemic Cytotoxic T Lymphocytes and Protective Immunity in Mice Against Intrarectal Recombinant HIV-Vaccinia Challenge," <i>Proc. Nat. Acad. Sci.</i> 95:1709-1714 (1998).			<input type="checkbox"/>
	AM	Berzofsky <i>et al.</i> , "Construction of Peptides Encompassing Multideterminant Clusters of Human Immunodeficiency Virus Envelope to Induce <i>In Vitro</i> T Cell Responses in Mice and Humans of Multiple MHC Types," <i>J. Clinical Invest.</i> 88:876-884 (1991).			<input type="checkbox"/>
	AN	Berzofsky and Berkower, "Novel Approaches to Peptide and Engineered Protein Vaccines for HIB Using Defined Epitopes: Advances in 1994-1995," <i>AIDS</i> 1995 9(A):S143-S157 (1995).			<input type="checkbox"/>
	AO	Bomsel, "Transcytosis of Infectious Human Immunodeficiency Virus Across a Tight Human Epithelial Cell Line Barrier," <i>Nature Medicine</i> 3:42-47 (1997).			<input type="checkbox"/>
↓	AP	Butini <i>et al.</i> , "Comparative Analysis of HIV-Specific CTL Activity in Lymphoid Tissue and Peripheral Blood," <i>J. Cellular Biochemistry Abstract Supplement</i> :147 (1994).			<input type="checkbox"/>
/NK/	AQ	Cranege <i>et al.</i> , "Macaques Infected with Live Attenuated SIVmac are Protected Against Superinfection via the Rectal Mucosa," <i>Virology</i> 229:143-154 (1997).			<input type="checkbox"/>

Examiner Signature	/Nicole Kinsey/	Date Considered	12/10/2007
--------------------	-----------------	-----------------	------------

¹EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 608. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

²Applicant's unique citation designation number (optional). ³Applicant is to place a check mark here if English language Translation is attached.

Substitute for form 1449A&B/PTO				<i>Complete If Known</i>	
				<i>Application Number</i>	10/815,340
				<i>Filing Date</i>	March 30, 2004
				<i>First Named Inventor</i>	Berzofsky, Jay A.
				<i>Art Unit</i>	1645
				<i>Examiner Name</i>	Nicole Kinsey
Sheet	3	of	5	<i>Attorney Docket Number</i>	015280-368240US

NON PATENT LITERATURE DOCUMENTS					
Examiner Initials *	Cite No. ¹	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.			T ²
/NK/	AR	di Tommaso <i>et al.</i> , "Induction of Antigen-Specific Antibodies in Vaginal Secretions by Using a Nontoxic Mutant of Heat-Labile Enterotoxin as a Mucosal Adjuvant," <i>Infection and Immunity</i> 64:974-979 (1996).			<input type="checkbox"/>
	AS	Douce <i>et al.</i> , "Intranasal Immunogenicity and Adjuvanticity of site-directed mutant derivatives of cholera toxin," <i>Infection and Immunity</i> 65:2821-2828 (1997).			<input type="checkbox"/>
	AT	Galligan <i>et al.</i> , "Long-Lived Cytotoxic T Lymphocyte Memory in Mucosal Tissues After Mucosal but not Systemic Immunization," <i>J. Exp. Med.</i> 184:1879-1890 (1996).			<input type="checkbox"/>
	AU	Graham <i>et al.</i> , "Candidate AIDS Vaccines," <i>New England Journal of Medicine</i> 333:1331-1339 (1995).			<input type="checkbox"/>
	AV	Hale <i>et al.</i> , "T Cell Multideterminant Regions in the Human Immunodeficiency Virus Envelope: Toward Overcoming the Problem of Major Histocompatibility Complex Restriction," <i>International Immunology</i> 1:409-415 (1989).			<input type="checkbox"/>
	AW	Haynes, B.F., "Scientific and Social Issues of Human Immunodeficiency Virus Vaccine Development," <i>Science</i> 260:1279-1286 (1993).			<input type="checkbox"/>
	AX	Klavinskis <i>et al.</i> , "Mucosal or Targeted Lymph Node Immunization of Macaques with a Particulate SIVp27 Protein Elicits Virus-Specific CTL in the Genito-Rectal Mucosa and Draining Lymph Nodes," <i>J. Immunol.</i> 157:2521-2527 (1996).			<input type="checkbox"/>
	AY	Kozlowski <i>et al.</i> , "Serum Angiotensin-1 Converting Enzyme Activity Processes a Human Immunodeficiency Virus 1 Gp160 Peptide for Presentation by Major Histocompatibility Complex Class I Molecules," <i>J. Exp. Med.</i> 175:1417- 1422 (1992).			<input type="checkbox"/>
↓	AZ	Langermann, S., "New Approaches to Mucosal Immunization," <i>Seminars in Gastrointestinal Disease</i> 7:12-18 (1996).			<input type="checkbox"/>
/NK/	BA	Lehner <i>et al.</i> , "Protective Mucosal Immunity Elicited by Targeted Iliac Lymph Node Immunization with a Subunit SIV Envelope and Core Vaccine in Macaques," <i>Nature Medicine</i> 2:767-775 (1996).			<input type="checkbox"/>

Examiner Signature	/Nicole Kinsey/	Date Considered	12/10/2007
--------------------	-----------------	-----------------	------------

¹EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

²Applicant's unique citation designation number (optional). ²Applicant is to place a check mark here if English language Translation is attached.

Substitute for form 1449A&B/PTO				Complete If Known	
				Application Number	10/815,340
				Filing Date	March 30, 2004
				First Named Inventor	Berzofsky, Jay A.
				Art Unit	1645
				Examiner Name	Nicole Kinsey
Sheet	4	of	5	Attorney Docket Number	015280-368240US

NON PATENT LITERATURE DOCUMENTS					
Examiner Initials *	Cite No. ¹	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.			T ²
/NK/	BB	Miller <i>et al.</i> , "Genital Mucosal Transmission of Simian Immunodeficiency Virus: Animal Model for Heterosexual Transmission of Human Immunodeficiency Virus," <i>J. Virol.</i> 63:4277-4284 (1989).			<input type="checkbox"/>
	BC	Modrow <i>et al.</i> , "Computer-Assisted Analysis of Envelope Protein Sequences of Seven Human Immunodeficiency Virus Isolates: Prediction of Antigenic Epitopes in Conserved and Variable Regions," <i>J. Virol.</i> 61:570-578 (1987).			<input type="checkbox"/>
	BD	Musey <i>et al.</i> , "HIV-1 Induces Cytotoxic T Lymphocytes in the Cervix of Infected Women," <i>J. Exp. Med.</i> 185:293-300 (1997).			<input type="checkbox"/>
	BE	Neutra <i>et al.</i> , "Antigen Sampling Across Epithelial Barriers and Induction of Mucosal Immune Responses," <i>Annu. Rev. Immunol.</i> 14:275-300 (1996).			<input type="checkbox"/>
	BF	Parditos <i>et al.</i> , "Antibody Responses to Non-Immunogenic Synthetic Peptides Induced by Co-Immunization with Immunogenic Peptides," <i>Immunology</i> 77:262-266 (1992).			<input type="checkbox"/>
	BG	Parditos <i>et al.</i> , "Mucosal Immunization with a Measles Virus CTL Epitope Encapsulated in Biodegradable PLG Microparticles," <i>J. Immun. Meth.</i> 195:135-138 (1996).			<input type="checkbox"/>
	BH	Parditos <i>et al.</i> , "The Adjuvant Effect of a Non-Toxic Mutant of Heat-Labile Enterotoxin of <i>Escherichia Coli</i> for the Induction of Measles Virus-Specific CTL Responses After Intranasal Co-Immunization with a Synthetic Peptide," <i>Immunology</i> 89:483-487 (1996).			<input type="checkbox"/>
	BI	Porgador <i>et al.</i> , "Intranasal Immunization with CTL Epitope Peptides from HIV-1 or Ovalbumin and the Mucosal Adjuvant Cholera Toxin Induces Peptide-Specific CTLs and Protection Against Tumor Development in Vivo," <i>J. Immunol.</i> 158:834-841 (1997).			<input type="checkbox"/>
↓	BJ	Shirai <i>et al.</i> , "Broad Recognition of Cytotoxic T Cell Epitopes from the HIV-1 Envelope Protein with Multiple Class I Histocompatibility Molecules," <i>J. Immunol.</i> 148:1657-1667 (1992).			<input type="checkbox"/>
/NK/	BK	Shirai <i>et al.</i> , "Helper-Cytotoxic T Lymphocyte (CTL) Determinant Linkage Required for Priming of Anti-HIV CD8+ CTL in Vivo with Peptide Vaccine Constructs," <i>J. Immunol.</i> 152:549-556 (1994).			<input type="checkbox"/>

Examiner Signature	/Nicole Kinsey/	Date Considered	12/10/2007
--------------------	-----------------	-----------------	------------

EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

¹Applicant's unique citation designation number (optional). ²Applicant is to place a check mark here if English language Translation is attached.

Substitute for form 1449A&B/PTO				Complete If Known	
INFORMATION DISCLOSURE STATEMENT BY APPLICANT				<i>Application Number</i>	10/815,340
<i>(Use as many sheets as necessary)</i>				<i>Filing Date</i>	March 30, 2004
				<i>First Named Inventor</i>	Berzofsky, Jay A.
				<i>Art Unit</i>	1645
				<i>Examiner Name</i>	Nicole Kinsey
Sheet	5	of	5	<i>Attorney Docket Number</i>	015280-368240US

NON PATENT LITERATURE DOCUMENTS					
Examiner Initials *	Cite No. ¹	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.			T ²
/NK/	BL	Takahashi <i>et al.</i> , "An Immunodominant Epitope of the Human Immunodeficiency Virus Envelope Glycoprotein Gp160 Recognized by Class I Major Histocompatibility Complex Molecule-Restricted Murine Cytotoxic T Lymphocytes," <i>Proc. Natl. Acad. Sci. USA</i> 85:3105-3109 (1988).			<input type="checkbox"/>
	BM	Takahashi <i>et al.</i> , "Induction of Broadly Cross-Reactive Cytotoxic T Cells Recognizing an HIV-1 Envelope Determinant," <i>Science</i> 255:333-336 (1992).			<input type="checkbox"/>
	BN	Takeshita <i>et al.</i> , "Molecular Analysis of the Same HIV Peptide Functionally Binding to Both a Class I and a Class II MHC Molecule," <i>J. Immunol.</i> 154:1973-1986 (1995).			<input type="checkbox"/>
↓	BO	Yamamoto <i>et al.</i> , "Mutants in the ADP-ribosyltransferase Cleft of Cholera Toxin Lack Diarrheogenicity but retain adjuvanticity," <i>J. Exp. Med.</i> 185:1203-1210 (1997).			<input type="checkbox"/>
/NK/	BP	Yamamoto <i>et al.</i> , "A nontoxic mutant of cholera toxin elicits Th2-type responses for enhanced mucosal immunity," <i>Proc. Natl. Acad. Sci. USA</i> 94:5267-5272 (1997).			<input type="checkbox"/>
					<input type="checkbox"/>
					<input type="checkbox"/>
					<input type="checkbox"/>
					<input type="checkbox"/>

Examiner Signature	/Nicole Kinsey/	Date Considered	12/10/2007
--------------------	-----------------	-----------------	------------

¹EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 808. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

²Applicant's unique citation designation number (optional). ²Applicant is to place a check mark here if English language Translation is attached.